Pilot and Feasibility Studies

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A self-management intervention for newly diagnosed with inflammatory arthritis: a randomized controlled feasibility and fidelity study

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Abstract

Background Inflammatory arthritis affects approximately 2–3% of adults worldwide. For patients newly diagnosed with arthritis, effective self-management is crucial, as they often face several physiological, emotional, and social challenges. A self-management intervention called NISMA was thus developed to cater to this group. This study aimed to evaluate the feasibility and fidelity of this intervention before conducting a full-scale randomized controlled trial.

Methods This feasibility study was conducted as a single-center randomized controlled trial. Twenty participants were expected to be sufficient for assessing the feasibility outcomes. The control group received only the usual care, while the intervention group received the NISMA intervention in addition, which involved individual and group sessions in a multidisciplinary setting. Feasibility was evaluated based on the recruitment, data collection, retention, and randomization processes. The patient-reported outcome measures and clinical measures were collected to review their potential for inclusion in a future randomized controlled trial. Fidelity was assessed by using documentation sheets filled in by the health professionals and audio recordings of the sessions to examine whether the intervention's principles and components were adequately addressed.

Results Among 47 eligible patients, we recruited 23 participants during a period of 4 months. The recruitment rate was 47% and the retention rate 91%. Randomization, although accepted, led to some disappointment in the control group. Data collection was effective, with only minimal missing data (< 1%). The fidelity was considered as high, as results indicated that nurses effectively engaged in collaborative partnerships with patients, utilizing planned questioning techniques and self-management strategies for problem-solving and resource utilization. However, action planning was inconsistently applied.

Conclusion The study demonstrated the feasibility and the overall high fidelity of delivering the NISMA intervention to patients newly diagnosed with inflammatory arthritis. The insights from the study are useful for identifying the areas that require modifications before initiating a randomized controlled trial.

Trial registration ClinicalTrials.gov ID: NCT06063252. Registered 02 October 2023 — retrospectively registered.

Keywords Rheumatoid arthritis, Axial spondyloarthritis, Psoriatic arthritis, Self-management, Feasibility, Fidelity

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Key messages regarding feasibility

- What uncertainties existed regarding feasibility?

This study faced several uncertainties regarding feasibility, including the recruitment pace and rate, the likelihood of patient adherence to the intervention, and the ability to collect the necessary data from both the intervention and control groups without significant missing data. Additionally, we were concerned about whether the healthcare professionals delivering the intervention could deliver it effectively, whether the education and training provided to them would be adequate, and whether the intervention could be seamlessly delivered into routine clinical practice.

- What are the key feasibility findings?

Over 4 months, 23 of 47 eligible patients were recruited, though enrolling those with axial spondyloarthritis proved challenging. While the initial assessments were completed, two patients did not complete the final assessment. Fidelity checks verified that healthcare professionals followed the intervention protocol.

- What are the implications of the feasibility findings for the design of the main study?

Addressing recruitment challenges and reducing time commitments for patients and healthcare professionals are essential. Ensuring fidelity of the intervention will be critical for the full-scale randomized controlled study. The next step involves a qualitative evaluation to gain deeper insights into the intervention's acceptability among patients and healthcare professionals.

Background

Inflammatory arthritis (IA) is a global health problem, occurring in 2–3% of the population [1–3]. The most common types of IA are rheumatoid arthritis (RA), axial spondyloarthritis (axSpA), and psoriatic arthritis (PsA) [1–3]. All of them significantly affect one's health [4, 5].

Despite the rise in the number of new drugs and treatment regimes, achieving complete, long-term disease remission remains a challenge for 20–40% of patients with IA [6–9]. Even among patients in remission, those with IA may still experience symptoms such as pain, stiffness, and fatigue. Due to IA's fluctuating nature, symptoms tend to come and go with varying intensity throughout one's lifetime [7]. Therefore, a significant yet often overlooked aspect of caring for patients with IA involves helping them understand their disease and develop effective strategies to manage its practical, physical, and psychosocial impacts. Self-management skills play a crucial role here [10].

The newly diagnosed patients are particularly challenged: on top of being diagnosed with a chronic illness that demands lifelong treatment, they are burdened by changes in their family role, work life, and social relationships [11, 12]. The European Alliance of Associations for Rheumatology recommends that newly diagnosed patients with RA have at least three to four appointments with a physician during the first year after diagnosis [13]. Moreover, to help these patients handle the numerous emotional, social, and physical challenges associated with IA (e.g., developing self-management skills), regular consultations and support from healthcare professionals (HPs) are needed [12, 14–19]. Previous research has also suggested that enhancing self-management—*an individual's ability to manage symptoms, treatments, physical and psychosocial consequences, and lifestyle changes inherent in living with a chronic condition* [20]—can significantly enhance the quality of life (QoL) of patients coping with chronic illness. However, systematic reviews of self-management interventions [10, 20–23] have yielded limited and varied effects, and these interventions were characterized by heterogeneous contents, settings, and outcomes. The comparability and applicability of these interventions across contexts are thus challenging, and the underlying mechanisms by which these interventions exert their impact remain relatively unclear [24–28].

We developed a self-management intervention that specifically targets patients newly diagnosed with IA. We employed a flexible approach guided by the four phases outlined in the Medical Research Council (MRC) framework for developing and evaluating complex interventions (development or identification of the intervention, feasibility, evaluation, and implementation) [29]. Our intervention was also informed by existing evidence and workshops with patients, managers, clinicians, and researchers. A description of the development process of the NISMA intervention (newly diagnosed with IA—a self-management intervention) is reported elsewhere [30].

In this study, we aimed to assess the feasibility and intervention fidelity of the NISMA intervention before initiating a full-scale randomized controlled trial (RCT) to investigate the intervention's efficacy.

We will report the intervention's acceptability, context, and its mechanisms of impact in our qualitative evaluation. Thus, in this study, we only report the intervention's feasibility and fidelity.

Methods

Design

This study was designed to evaluate progression criteria in preparation for a full-scale RCT and to identify areas where adjustments of the intervention and/or study design were needed. Our progression criteria included a 50% recruitment rate of all patients approached, an 85% retention rate, and overall high fidelity.

The study was designed as a single-center randomized controlled feasibility study (allocation ratio: 1:1). It is reported according to the CONSORT extension [31] to randomized pilot and feasibility trials.

Setting, participants, randomization, and blinding

The intervention was conducted at the Center for Rheumatology and Spine Diseases, Rigshospitalet, Denmark, from December 2021 to February 2023. The inclusion criteria were as follows: adults (≥ 18 years) diagnosed with RA (ICD10 diagnoses: M05.9, M06.0, M06.9), axSpA (ICD10 diagnoses: M45.9, M46.1, M46.8, M46.9), or PsA (ICD10 diagnoses: M073.A, M073.B) in the last 6 months. The exclusion criteria included those with insufficient Danish language skills to actively participate in the sessions and undergoing chemotherapy treatment for malignant diseases.

We performed simple randomization using the Research Electronic Data Capture (REDCap) software's randomization module [32]. Due to the nature of our intervention, participant and clinician blinding was not possible.

Sample size

Recommendations for sample sizes in feasibility studies typically range between 24 and 30 participants [33, 34]. Therefore, we initially opted for 30 participants evenly split between the control and intervention groups, as this number would allow a manageable and thorough evaluation of study logistics and feasibility without overextending resources. However, waiting lists caused by COVID-19 and a subsequent nationwide nursing strike, which increased pressure on the Danish healthcare system, led us to revise our approach. Consequently, we adjusted our target to 10 participants in each group. Although not optimal, this revised sample size was considered adequate to provide reasonable estimates of key feasibility parameters, including recruitment efficiency, data collection methods, participant retention, the effectiveness of randomization, and the standard deviation of primary outcomes. Anticipating a participant retention rate of 85%, we estimated that a target sample of 20 would allow us to calculate retention with a margin of error of approximately 17% at a 95% confidence level. This adjusted sample size was deemed sufficient to guide the design of a future RCT and to support a meaningful analysis of the study's progression criteria.

Our primary objective was not to achieve statistical power for detecting changes in health outcomes but rather to focus on evaluating feasibility, regulatory, and statistical factors [33].

Interventions

Participants in the control group received usual care, and participants in the intervention group received usual care supplemented with the NISMA intervention.

Usual care consisted of planned sessions with a rheumatologist and occasionally a rheumatology nurse. Those who initiated pharmacological treatment (methotrexate) had an appointment with a nurse and a follow-up phone call. All the patients could contact the outpatient clinic and talk to a nurse.

The NISMA intervention was 9 months long. For our theoretical framework, we used the social cognitive theory [35, 36], and to support the enhancement of self-efficacy, we used acceptance and commitment therapy (ACT) [37]. The intervention involved four individual face-to-face 1-h sessions with a nurse and two 2-h group sessions (five to seven patients) with a nurse, an occupational therapist (OT), and a physiotherapist (PT), with the nurse being the facilitator. During every session, a specific topic was chosen for discussion (Fig. 1), and a

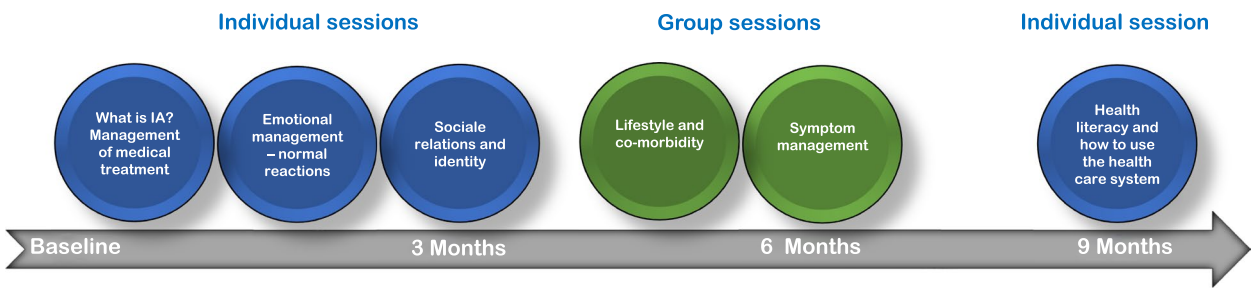

Fig. 1 Session overview of the NISMA intervention

person-centered approach was used to address individual problems and secure relevance of the intervention.

To ensure the fidelity of the intervention, we developed a comprehensive manual, and to secure the validity of its content, our experts in rheumatology and self-management (members of the project group) reviewed the manual. Then, to evaluate the applicability of the manual and the extent to which the HPs understood its content, we conducted two cognitive focus-group interviews [38]: the first with nurses and the second with all the HPs who delivered the intervention. The HPs found the manual understandable and deemed it applicable to clinical practice. The cognitive interviews did not contribute to significant changes in the manual. Further, to train the HPs to deliver the intervention and hone their skills, we designed a 2-day competence development program based on the relevant literature and the HPs' responses to a brief questionnaire about their strengths and weaknesses regarding the intervention components. To further increase fidelity, we offered the HPs ongoing supervision with both the project manager (L. H. L.) and a psychologist trained in ACT.

Feasibility and fidelity outcomes

We investigated *feasibility outcomes—recruitment, data collection, attendance, retention, and randomization*—and the feasibility of assessing *patient-reported outcome measures* (PROMS) and *clinical measures* (anthropometric and cardio-metabolic measures) to identify suitable outcomes for future RCTs.

A rheumatologist or rheumatology nurse from the outpatient clinic briefly informed the eligible patients about the study. If a patient expressed interest, they were provided with additional details through both oral and written participant information. All the patients were screened for eligibility according to the inclusion and exclusion criteria.

We closely monitored the recruitment procedure by assessing various factors, including the number of eligible patients, the time it took to recruit them, the clinicians' willingness to engage in recruitment, the patients' willingness to participate, the characteristics of those who consented to participate, and the reasons of those who did not.

Since the intervention was 9 months long, we were interested in the retention rates, particularly those in the control group. Moreover, we were interested in evaluating methods used for outcome assessments and data collection, the response rates of the questionnaires, and the amount of missing data.

The nurses who delivered the intervention were responsible for booking and planning new sessions. As such, we documented whether the participants attended each session (attendance) and completed the study, including the final outcome assessment (retention) and how much time the HPs spent on each participant. Moreover, we evaluated participants' responses to randomization and group allocation, particularly those assigned to the control group.

After exploring the literature and conducting several discussions in the project group, we chose the PROMs that are relevant for patients newly diagnosed with IA and are suitable as outcome measures in self-management interventions. More details about the PROMs have been described elsewhere [30]. We tested the feasibility of the following patient-reported outcome measures both at baseline and after completing the intervention.

We measured *physical activity* using the Physical Activity and Sedentary Time questionnaire (FAST) [39], *functional status* using the Multidimensional Health Assessment Questionnaire (MDHAQ) [40], *pain* using the visual analog scale for pain (VAS-pain) [41], *fatigue* using the Bristol Rheumatoid Arthritis Fatigue Questionnaire (BRAF-Numerical Rating Scales (NRS)) and the visual analog scale for fatigue (VAS-fatigue) [42, 43], *health literacy* using the Health Literacy Questionnaire (HLQ) [44], *quality of life* using the EuroQol-5 Dimension (EQ5D) questionnaire [45], *illness perception* using the Brief Illness Perception Questionnaire (B-IPQ) [46], *self-efficacy* using the Arthritis Self-Efficacy Scale (ASES) [47], *anxiety and depression* using the Hospital Anxiety and Depression Scale (HADS) [48], and *illness intrusiveness* using the Illness Intrusiveness Rating Scale (IIRS) [49].

We also evaluated the feasibility of assessing clinical outcome measures, such as total cholesterol and glycated hemoglobin (HbA1c), using blood samples and height, weight, and blood pressure. Our evaluation also included patients' tolerance to these measures.

We obtained the data on disease activity from the Danish rheumatology database DANBIO [50, 51] and patient medical records, utilizing the nearest measure to baseline assessment. We used the following composite scores: Disease Activity Score in 28 joints (DAS28) [52], the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) [53], and the Disease Activity index for Psoriatic Arthritis (DAPSA) [54].

Regarding fidelity, we examined whether our planned intervention principles and components were addressed by the HPs (two nurses: one OT and one PT) delivering the intervention.

In alignment with the logic model of our intervention developed during the development phase [30], we focused on different intervention components to assess fidelity. These included the establishment of a partnership between patients and HPs, a patient-centered approach,

guidance in decision-making, problem-solving, action planning, the use of ACT-questioning techniques, the enhancement of knowledge about IA, the management of social relations and support in engaging with relatives, psychoeducation and emotional management, symptom management, lifestyle management, and the exchange of experiences with other patients in group sessions.

Data collection

We collected the sociodemographic data at baseline, and the project manager (L. H. L.) collected the outcome data—including the clinical measures—at baseline and at the end of the 9-month intervention. The participants entered the self-administered questionnaires on an iPad, using the REDCap tools hosted in the Capital Region of Denmark [55, 56]. The project manager had access to the questionnaire data and were therefore able to obtain missing data, if any, immediately after questionnaire completion.

In collaboration with the outpatient clinic, we registered the number of participants deemed to be eligible during the recruitment period and session attendance in the intervention group.

To monitor and determine intervention fidelity, e.g., the extent to which the intervention was delivered by the HPs as intended, the nurses filled out documentation sheets after delivering each individual session (Supplementary Material 1). This was supplemented by audio recordings of individual and group sessions.

The intervention components that we evaluated for fidelity helped us develop the documentation sheets and the templates for analyzing the audio recordings (Table 1). To ensure a balanced collection of data from the audio recordings, we randomly selected six sessions, evenly distributed over the intervention period, ensuring the representation of all session types. Thus, the recordings were distributed across four individual sessions (two with each nurse) and two group sessions. The project manager informed the nurses about the sessions for which we needed audio recordings, and the nurses handled the recordings.

Analysis of feasibility and fidelity data

We analyzed the recruitment rates, attendance, retention, data completion, and data collection methods at the end of the intervention. Our primary analyses focused on feasibility outcomes, but we also used descriptive statistics on the PROMs to assess the characteristics of our sample, including median, mean (M), and standard deviation (SD) for continuous data and frequency (%) for categorical data. We performed our calculations using the SAS software (v. 9.3; SAS Institute Inc., Cary, NC, USA).

Using the documentation sheets for fidelity, we analyzed how frequently the intervention components were used. We have reported the results using the number and percentage of the components' appearance in the 43 individual sessions conducted (excluding one participant who withdrew from the intervention after the initial group session).

To analyze the audio recordings, the first author listened to them and made corresponding notes in the provided template. The findings were subsequently discussed with the second and the last author. We evaluated whether each intervention component was implemented as planned, partly implemented, or not implemented at all. We also explored whether the HPs introduced any supplementary activities—activities not described in the manual—during the intervention [57].

Results

Feasibility results

The recruitment process commenced on November 1, 2021, preceded by the training of HPs in October 2021. Over 4 months, 49 patients were screened, and 47 were deemed eligible for inclusion. Of these, 23 agreed to participate and were enrolled in the study, resulting in a recruitment rate of 47% among those approached and 49% among those eligible.

The primary reason of the patients who declined participation was lack of time, with some patients who had already taken several sick leaves being concerned about having to ask for more time off from work (Fig. 2).

Patients were primarily recruited when they came for a consultation with the nurse regarding the initiation of pharmacological treatment (methotrexate). This strategy proved effective in recruiting patients with RA and PsA but not axSpA, as patients with axSpA are not treated with methotrexate. At the end of the first 4-month period of the study, no patients with axSpA were enrolled, so we involved the rheumatologists, and, consequently, two patients with axSpA patients were included.

There were no major differences in demographic characteristics between the participants in the control group and the intervention group (Table 2), but it appeared that the control group participants were slightly better educated. There were some differences in clinical variables, with the intervention group displaying elevated levels of anxiety and depression and higher levels of illness intrusiveness.

Most of the participants (19/23) had systemic injections with glucocorticoids before baseline assessment (Table 2). The most frequently reported current and previous comorbidity was hypertension, followed by heart disorders, asthma, and depression (data not shown).

Table 1 Fidelity analysis

Components in the intervention used as templates for analysis	Documentation sheets (only individual sessions) ($n=43$)		Fidelity assessment	Audio recordings of the sessions Four observations (audio recordings) of the individual sessions and two of the group sessions
	Topics	Addressed in % of sessions		
Establishment of patient and HP partnership[A]	Create partnership	32/43 = 76%	IP	The nurses focused on establishing a connection with the participants and reaching a mutual understanding The nurses introduced the form in the sessions in a single session. We only had one audio recording from session 1
	Encourage sharing of medical history	29/43 = 67%	IP	
	Introduce the form in the sessions	27/43 = 63%	IP	
	Introduce self-management	15/43 = 35%	IP	
Patient-centered sessions Decision-making, problem-solving, and action planning	Identification of individual problems	38/43 = 88%	IP	The HPs consistently used a patient-centered approach (which was identified in all the audio recordings) in which the participants were the central focus and influenced the content of the sessions The HPs provided support and embraced an appreciative approach throughout the sessions. In all the sessions, the HPs identified individual issues with the participants. However, they did not systematically use action planning
	Handling IA-related issues	33/43 = 77%	IP	
	Working with problem-solving	25/43 = 58%	IP	
	Work with action planning	3/43 = 7%	NI	
Use of ACT-questioning techniques for reflection	Mirroring	43/43 = 100%	IP	The HPs utilized all the listed ACT-questioning techniques
	Mentalizing sentences	38/43 = 88%	IP	
	Appreciative phrasing	42/43 = 98%	IP	
	Questions about values	33/43 = 77%	IP	
Enhancement of knowledge about IA, including treatment, side effects, and flare	Inflammatory arthritis	37/43 = 86%	IP	The HPs explained information about IA and its treatment, ensuring that participants had a clear understanding of their arthritis and the prescribed treatment. The enhancement of disease knowledge was consistently present in all the audio recordings
	Pharmacological treatment	37/43 = 86%	IP	
	Side effects	36/43 = 83%	IP	
Management of social relations and helping to engage relatives	Family	41/43 = 95%	IP	The HPs addressed questions about the effect of arthritis on participants' family and work life. They also asked whether the participants received the necessary support from their relatives and employees
	Occupation	33/43 = 77%	IP	
	Friends	24/43 = 56%	IP	
	Leisure activities	38/43 = 88%	IP	
Psychoeducation and emotional management	Common grief and crisis reactions	21/43 = 49%	IP	The nurses introduced a discussion about typical emotional reactions in session 2; however, discussions on frustrations and concerns also occurred in most of the other sessions
	Affected mood	35/43 = 81%	IP	
	Concerns, etc	27/43 = 63%	IP	

Table 1 (continued)

Components in the intervention used as templates for analysis	Documentation sheets (only individual sessions) ($n=43$)		Fidelity assessment	Audio recordings of the sessions Four observations (audio recordings) of the individual sessions and two of the group sessions
	Topics	Addressed in % of sessions		
Symptom management	Flares	35/43 = 81%	IP	The HPs addressed the management of flares, fatigue, sleep disturbances, and pain with the participants. Breathing exercises and relaxation exercises were mentioned to manage pain, but there was no systematic approach to symptom management, such as using energy accounts or a symptom diary Additionally, the HPs informed participants about how pain and fatigue could impact their moods
	Fatigue	32/43 = 74%	IP	
	Management of energy	18/43 = 42%	PI	
	Pain	40/43 = 93%	IP	
	Sleep	31/43 = 72%	IP	
	Symptom diary	2/43 = 5%	NI	
Lifestyle	Diet	33/43 = 77%	IP	The HPs responded to participants' interests in diets. Recommendations for healthy diets were addressed in both individual and group sessions. The HPs also discussed the need for physical activity, recognizing that many participants were uncertain about which activities that were suitable and that should be avoided
	Smoking	14/43 = 33%	IP	
	Alcohol	14/43 = 33%	IP	
	Physical activity	36/43 = 83%	IP	
Exchange of experiences with other patients in group sessions (only based on audio recordings)	The HPs encouraged the participants to openly share their experiences with each another. The audio recordings revealed that effective facilitation skills were crucial in conducting group sessions, and facilitation was only partly succeeded in the first session. During this session, the participants discussed their own (sometimes less pleasant) experiences with the healthcare system instead of focusing on their management strategies. Notably, one group, characterized by a more respectful tone, had better group dynamics. This was a situation the HPs did not have much control over **The audio recordings revealed that the group sessions were implemented as planned**			

Abbreviations: *ACT* acceptance and commitment therapy, *IA* inflammatory arthritis, *IP* implemented as planned, *PI* partly implemented, *NI* not implemented at all.
[A]Primarily relevant in the first session

All the participants successfully completed the baseline assessments. However, one male participant from the intervention group could not be contacted immediately after baseline. Additionally, another male participant from the control group, despite being contacted three times through different channels (e-mail and phone), was lost to follow-up. A third male participant from the intervention group withdrew after the first group session, despite completing the post-intervention assessment. His withdrawal was partly due to extremely high disease activity and partly because he felt he had very little in common with the other participants. Consequently, 10 out of 12 participants in the intervention group completed the intervention. Overall, 21 participants completed the post-intervention assessment, including both self-reported and clinical measures, resulting in an outcome assessment retention rate of 91%.

The nurses who delivered the intervention were responsible for booking the session in collaboration with the participants and for rebooking if a session was cancelled. The main reason for cancellation was sickness. Occasionally, lack of resources or time limitations among HPs resulted in other tasks being prioritized, but the sessions were never cancelled due to lack of time. On average, approximately 6.4 HP working hours were allocated per participant during the intervention. This included time spent on competence development, supervision, and preparation for, and conduction of the sessions.

The participants who completed the intervention attended all the sessions. Though they were informed that online meetings were a possibility, they expressed a preference for in-person meetings.

Randomization via REDCap was feasible. All the participants accepted randomization, but some expressed

significant disappointment when they learned that they had been assigned to the control group. They strongly felt that they needed help in managing their newly diagnosed IA.

The data collection methods were deemed to be appropriate, as there were very little missing data in the PROMs with less than 1% missing data. Immediately after questionnaire completion, we asked the participants to fill in the missing data. The participants were willing to give their blood samples and undergo blood pressure, height, and body weight measurements. Moreover, we found it feasible to retrieve the data on disease activity from DANBIO and the blood sample results from patient medical journals. Some participants in the control group almost forgot that they were study participants, as there were 9 months between baseline and the post-intervention assessment. The rest of the participants responded to our first or second inquiry (e-mail or phone call), which was approximately 14 days apart.

Fidelity results

The fidelity results revealed that the nurses strove to establish a collaborative partnership with the patients and used the questioning techniques they had been trained in and the self-management enhancement strategies for problem-solving and resource utilization. However, they did not systematically use action planning.

The sessions covered a range of topics, including information about the participants' condition and health needs, promoting healthy behaviors to minimize the impact of arthritis, encouraging participants to seek social support, addressing the emotional impact of arthritis, and achieving balance in life. The HPs stayed true to the planned topic for each session and responded to the issues raised by the participants. The flexibility of this approach was evident in the observation sheets, which revealed that many topics recurred in multiple sessions, indicating that the nurses revisited previous discussions and that the patients' current situation guided the discussions. As a result, fidelity was assessed as high overall.

In 17 of the 43 individual sessions, the nurses noted that a significant amount of time was allocated for the sessions. In certain cases, some part of the time was spent on small talk, especially when the participants had only minor arthritis-related difficulties.

Discussion

The NISMA intervention is feasible and has a high level of fidelity

In total, 49% of the eligible patients were willing to participate. Patients' primary reason for declining participation was that they perceived the intervention to be time-consuming, and they were concerned about requesting more time off from work, especially as some of them had already taken several sick leaves. Offering online sessions could be a viable solution for this. Our fidelity analysis revealed that in 40% of the individual sessions, nurses reported excess time allocation, suggesting that shorter, more efficient sessions could be conducted without compromising quality. Initially, considering the vulnerability of the newly diagnosed in adapting to chronic illness, we allocated ample time for sessions. Thus, based on the insights from this feasibility study, future RCT sessions should be shorter, and the 6.4 h that HPs spend per patient should be reduced.

The participants who completed the intervention attended all the scheduled sessions. In the control group, one participant was lost to follow-up. In the intervention group, two male participants dropped out: one right after baseline and one after the first group session. Interestingly, one of them was the only male participant below 35 years of age we managed to recruit. Unfortunately, we do not know why he dropped out. This could suggest that our intervention components might not be attractive to younger males, indicating the need for a different approach to accommodate their preferences. A systematic review [58] found that online peer-support and group sessions are effective components of self-management interventions for young people with chronic conditions. This suggests that a more diverse range of programs and platforms is necessary to effectively reach and include all newly diagnosed patients.

Our sample had a higher proportion of participants with a high educational level (65%) compared to the general Danish population (42%) [59]. While this may be due to chance given the small sample size, it aligns with findings from a systematic review [60] indicating that individuals with lower socioeconomic status are less likely to participate in self-management interventions. This discrepancy may be attributed, to less flexible working hours, but could also stem from the demanding nature of interventions such as ours, which require significant time and personal engagement. Previous studies [61, 62] have suggested that self-management interventions may unintentionally exacerbate disparities by not adequately considering participants' capacities. Addressing this challenge will be a key focus of our future RCT.

The abovementioned systematic review [60] also noted high dropout rates among patients with low socioeconomic status in group interventions and highlighted the effectiveness of individualized interventions in addressing this issue. In our intervention, which comprised a mix of individual and group sessions, we observed a 13% dropout rate (3/23), which was deemed acceptable [63]. Notably, none of the dropouts came from lower

socioeconomic backgrounds, raising the question of whether dropout rates would increase with a more socioeconomically diverse participant pool.

Overall, we determined that the intervention fidelity was high. Specifically, the content, frequency, duration, and questioning techniques adhered to the guidelines outlined in the intervention manual. Our evaluation also highlighted the HPs' considerable efforts to respect the session topics and accommodate the participants' individual needs. They effectively assisted the participants in problem identification and management. Since problem-solving and action planning are core self-management strategies for achieving self-management skills [25], it is worth noting that action planning was documented in only 3% of the sessions—this could be attributed to the nature of certain problems, which may not always be suitable for being addressed through action planning. Additionally, it is pertinent to mention that our manual lacked explicit guidance on action planning, an aspect that did not receive significant emphasis in the competence development program. Consequently, if we determine its relevance in an RCT, the project group should consider strongly focusing on action planning.

To ensure that our intervention was implemented with great fidelity, we developed a detailed manual and a competence development program and provided continuous supervision. Research suggests [64] that interventions with specific guidelines/manuals are implemented with higher fidelity than vaguely described ones. While our approach was naturally driven by the principle of tailoring content to accommodate the participants' current situation and needs, it led the intervention in diverse directions, posing challenges for HPs. A notable strength was the intervention's flexibility, allowing nurses to revisit critical topics and address participants' problems effectively.

The manual also described the group sessions as relatively flexible. These sessions aimed to address symptoms and lifestyle issues and enable participants to share their experiences. While this aim was partially achieved, a tighter facilitation of the sessions and fewer casual conversations could have ensured a more effective use of time. Facilitating group sessions is a challenging task [65], and the HPs did not receive much preparation and practice beforehand. Becoming a proficient facilitator is thus a learning process, and it is crucial for a future RCT to prioritize adequate preparation and training for HPs in group facilitation.

The participant who withdrew after the first group session expressed that his expectations regarding peer experiences were not met. This highlights the need for clearer information and better alignment of participant expectations. This also raises critical questions for future considerations, including the necessity of mandatory group sessions, the option of offering the intervention with or without these sessions in the upcoming RCT, and the potential for stratifying sessions by factors such as diagnosis or age. These aspects will be thoroughly explored in a forthcoming qualitative evaluation.

As outlined in the background section, offering self-management interventions to patients with chronic diseases may seem logical, yet the effectiveness of such interventions varies widely [66–70]. Studies suggest that interventions tailored to specific diseases tend to outperform generic ones [67]. In line with this, our approach involved designing and testing an intervention not only uniquely tailored to patients with IA but also specifically to the needs of those who are newly diagnosed. We posited that early intervention could prevent the establishment of unhealthy habits, and that substantial emotional support is crucial immediately after diagnosis. The NISMA intervention provides crucial assistance during this vulnerable time. While the specific content of the NISMA intervention largely aligns with existing self-management strategies, its unique aspect also lies in the extended duration of support. Previous self-management interventions, often lasting 6–8 weeks, have generally resulted in significant but short-term effect [23, 71]. In contrast, research indicates that interventions of a longer duration, measured in months, are associated with more substantial and lasting health outcomes [72, 73]. Additionally, extended interventions, particularly those lasting 6–12 months, have been observed to reduce health disparities [60].

In our quest to improve self-management for newly diagnosed individuals, it is clear that there is no one-size-fits-all solution, and even though the NISMA is tailored and flexible, the recruitment rate tells us that it is not appealing to all newly diagnosed individuals in its current form. The development of a universally appealing intervention for all newly diagnosed individuals is unlikely. Thus, there is a clear necessity for new research across various domains. Specifically, there is a need to explore and understand the preferences for self-management interventions among those with axSpA. They are generally younger at the time of diagnosis, and the proportion of men with axSpA is higher compared to patients with RA and PsA.

Based on the feasibility and fidelity results, proceeding to a full trial appears both possible and reasonable. However, we will conduct a more thorough analysis of the participants' perspectives regarding their expectations and perceived benefits from the intervention in the qualitative evaluation. We will also explore the context and acceptability of the intervention and the potential mechanisms of its impact. Such knowledge will help us

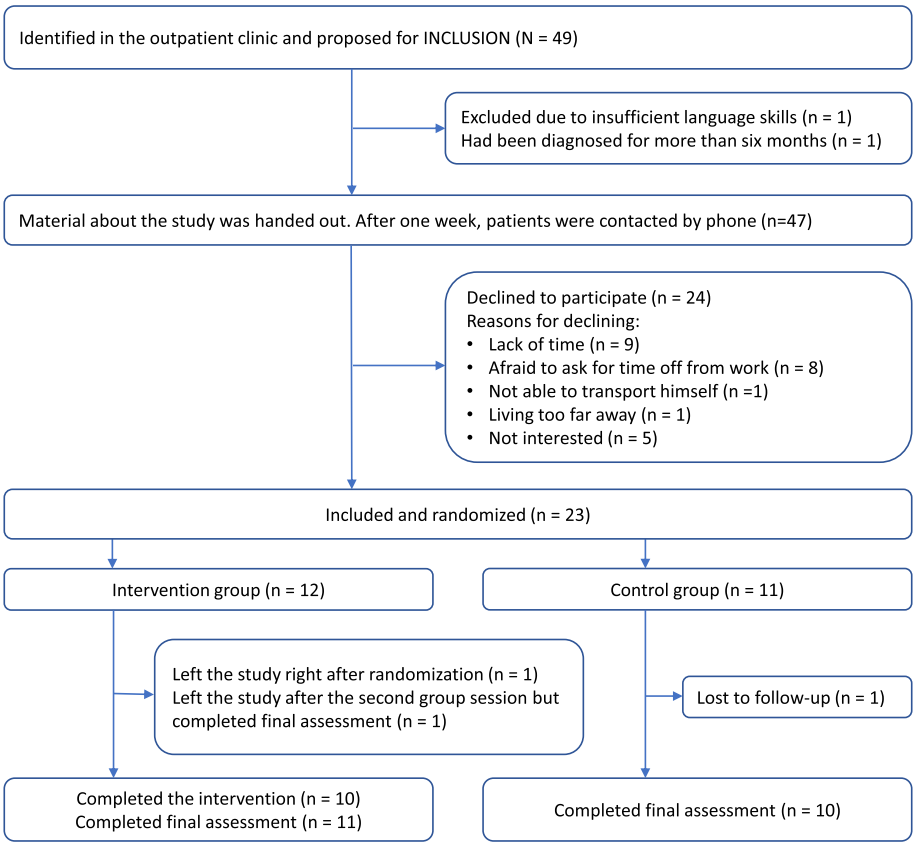

Fig. 2 Flow diagram of enrolment, allocation, and assessments

further develop the intervention. Moreover, adjustments to the intervention content may be necessary to better align it with our clinical setting. For instance, we learned that a reduction in the time commitment required from patients and HPs is relevant. Implementing such adjustments will improve the likelihood of the intervention being fully implemented as planned, and if it proves efficient in generating clinically significant changes and is economically viable, it can be fully integrated in clinical practice.

This study had several limitations. The primary limitation was the smaller sample size, which fell below the recommended range of 24–30 participants for feasibility studies [33, 34]. This limitation resulted in a higher degree of imprecision when evaluating retention rates. Additionally, the number of participants with axSpA was particularly limited. Thus, our sample may not fully capture the entire spectrum of experiences or challenges that could arise in a larger-scale implementation of our intervention. There is also a potential for selection bias in participants who volunteer for feasibility studies, as such participants may be more motivated or more resourceful, as also suggested by the high proportion of participants with high socioeconomic status in this study.

Regarding recruitment, we found no ideal way to recruit patients with axSpA. The pathway to diagnosis and treatment initiation differs between axSpA, RA, and PsA patients. However, we believe that some patients with axSpA could benefit from an intervention like NISMA. A recent cross-sectional study [74] of mental health in patients with IA found that newly diagnosed patients with axSpA were particularly vulnerable. Identifying a new recruitment strategy for patients with axSpA is thus essential before conducting a future RCT study. Another limitation lies in our findings. Like other self-management intervention studies, our findings may be highly context specific, making it challenging to generalize them to different settings or populations. However, this contextual specificity can also be considered a strength. Conducting the intervention in a clinical practice setting rendered the findings highly applicable, allowing us to identify the practical challenges and barriers that could potentially hinder the successful implementation of the intervention. Furthermore, this context facilitated an iterative development of the intervention,

Table 2 Baseline characteristics

Variables	Intervention group (*n* = 12)	Control group (*n* = 11)	Total (*n* = 23)
Age, mean (SD) (range)	52.7 (18.1) (24–76)	53.6 (18.6) (27–81)	53.1 (18.0) (24–81)
Female, *n* (%)	6 (50)	7 (64)	13 (57)
Diagnoses, *n* (%)			
Rheumatoid arthritis	7 (59)	9 (82)	16 (70)
Psoriatic arthritis	4 (33)	1 (9)	5 (22)
Axial spondyloarthritis	1 (8)	1 (9)	2 (8)
Disease activity, mean (SD)			
DAS28[a] (RA only)	3.6 (1.9)	3.6 (2.1)	3.6 (2.0)
DAPSA[b] (PsA only)	29.9 (16.1)	21.0 (-)	28.1 (14.5)
BASDAI[c] (axSpA only)	41.0 (-)	69.0 (-)	55.0 (19.8)
Pharmacological treatment, *n* (%)			
DMARD[d]	12 (100)	10[e] (91)	22 (96)
Glucocorticoids (betamethasone injection)	10 (83)	9 (82)	19 (83)
Pain medications at a daily level	4 (33)	4 (36)	8 (35)
Pain medications at a weekly level	3 (25)	1 (9)	4 (17)
Clinical measures, mean (SD)			
Cholesterol (total)	5.2 (0.6)	4.8 (0.8)	5.0 (0.7)
HbA1c[f] (mmol/mol)	40.8 (10.6)	38.6 (5.6)	39.7 (8.4)
Systolic blood pressure	136.1 (17.2)	133.8 (23.2)	135.0 (19.9)
Diastolic blood pressure	83.1 (14.0)	83.5 (14.3)	83.3 (13.8)
Body weight (kilograms)	83.1 (17.4)	83.5 (18.2)	83.3 (17.4)
Co-habitant status, *n* (%)			
Living alone	1 (8)	3 (27)	4 (17)
Educational level, *n* (%)			
Primary school	2 (17)	-	2 (9)
High school or short education	4 (33)	2 (18)	6 (26)
Short higher education	2 (17)	4 (36)	6 (26)
Medium or long higher education	4 (33)	5 (45)	9 (39)
Yearly household income in American dollars, *n* (%)			
More than US $88,000	5 (42)	6 (55)	11 (48)
Occupation, *n* (%)			
Employed or in training	8 (67)	7 (64)	15 (65)
Retired (because of age or disease)[g]	5 (42)	4 (36)	9 (39)
Smoking daily, *n* (%)			
Yes	5 (42)	1 (9)	6 (26)
Alcohol, *n* (%)			
Never	3 (25)	2 (18)	5 (22)
Monthly	5 (42)	6 (55)	11 (48)
Weekly	4 (33)	3 (27)	7 (30)
Physical activity, *n* (%)			
Less than 2½ h of moderate to hard PA[h] per week	8 (67)	8 (73)	16 (70)
More than 2½ h of moderate to hard PA[h] per week	4 (33)	3 (27)	7 (30)
Patient-reported outcome measures, mean (SD)			
Physical disability/function, MD-HAQ[i]	0.5 (0.5)	0.4 (0.3)	0.5 (0.4)
Pain, VAS[j]	44.3 (26.5)	31.2 (24.7)	38.0 (25.9)
Fatigue, VAS[j]	49.9 (26.1)	52.7 (17.2)	51.3 (21.8)
Severity of fatigue, BRAF-NRS[k]	6.0 (1.8)	6.3 (1.6)	6.1 (1.6)

Table 2 (continued)

Variables	Intervention group ($n=12$)	Control group ($n=11$)	Total ($n=23$)
Effect of fatigue, BRAF-NRS[k]	6.3 (1.9)	5.3 (1.4)	5.8 (1.7)
Coping with fatigue, BRAF-NRS[k]	4.1 (1.4)	4.1 (2.1)	4.1 (1.7)
Having sufficient information to manage health, HLQ[j]	2.8 (0.5)	2.9 (0.6)	2.9 (0.5)
Actively managing health, HLQ[l]	2.6 (0.5)	2.7 (0.3)	2.6 (0.4)
Social support for health, HLQ[l]	3.0 (0.6)	3.1 (0.4)	3.0 (0.5)
Ability to actively engage with healthcare providers, HLQ[l]	3.9 (0.7)	4.0 (0.6)	4.0 (0.6)
Health-related quality of life, EQ5D[m]	0.7 (0.3)	0.9 (0.1)	0.8 (0.2)
Illness perception, B-IPQ[n]	5.9 (1.4)	4.0 (1.4)	5.0 (1.7)
Pain self-efficacy, ASES[o]	4.9 (1.8)	5.0 (1.1)	5.4 (1.5)
Other symptoms self-efficacy, ASES[o]	5.0 (1.9)	6.9 (0.9)	5.9 (1.8)
Anxiety, HADS-A[p]	7.1 (3.5)	3.9 (2.7)	5.6 (3.5)
Depression, HADS-D[p]	5.3 (3.7)	3.2 (2.9)	4.3 (3.4)
Illness intrusiveness, IIRS[q]	42.4 (16.1)	28.9 (9.7)	35.6 (15.0)

[a] Disease Activity Score in 28 joints with erythrocyte sedimentation rate

[b] Disease Activity index for Psoriatic Arthritis

[c] Bath Ankylosing Spondylitis Disease Activity Index

[d] Disease-modifying antirheumatic drug

[e] One participant was only treated with ibuprofen

[f] Glycated hemoglobin

[g] One participant had an early retirement and was part-time employed

[h] Physical activity

[i] Multidimensional Health Assessment Questionnaire

[j] Visual analog scale

[k] Bristol Rheumatoid Arthritis Fatigue Questionnaire Numerical Rating Scale

[l] Health Literacy Questionnaire

[m] EuroQol-5 Dimension

[n] Brief Illness Perception Questionnaire

[o] arthritis-specific self-efficacy measurement tool

[p] Hospital Anxiety and Depression Scale

[q] Illness Intrusiveness Rating Scale

enabling us to refine and enhance its effectiveness based on the challenges we identified.

Conclusion

This randomized controlled feasibility study proved the feasibility of delivering the NISMA intervention and demonstrated its high fidelity. We considered our progression criteria met, with a recruitment rate of 47% (slightly below target), a retention rate of 91%, and a high level of fidelity. Our next step involves defining and describing the necessary adjustments, which include identifying effective recruitment strategies for patients with axSpA, modifying the time spent on the intervention, and strengthening the HPs' competences in conducting group sessions and utilizing ACT questioning. These adjustments will help us prepare for initiating a fully powered RCT to test the efficacy and cost-effectiveness of our intervention.

Patient research partner

As recommended by EULAR [75], we involved patient research partners (PRP) in this feasibility study. Our reporting on the involvement of a PRP in the trial followed the GRIPP2-short form [76]. A PRP was involved to ensure that a patient's perspective was maintained throughout the study. Our involved PRP was a patient with newly diagnosed RA. She was involved in the design of the study and the final decisions regarding its outcomes and offered feedback on instruments and questionnaires. Further, she read, commented on, and approved the participant information for this trial. Moreover, she commented on the "Results," the "Discussion," and the "Conclusion" sections. Her own experiences of being newly diagnosed with RA was significant in shaping this trial.

Adverse events

This was a nondrug intervention study, which included educational components, behavioral therapies, and self-efficacy training strategies—the components that are included in the daily work of many HPs. No adverse events occurred.

Supplementary Information

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Supplementary Material 1. Documentation sheet: Individual sessions in NISMA.

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Authors' contributions

All the authors contributed to the design of the study. LHL led the project in close collaboration with BAE. All the authors (LHL, TT, AT, MA, MLH, SDK, and BAE) contributed substantially to the data analysis. LHL drafted the manuscript with BAE and TT. All the authors read, critically revised, and approved the final version of the manuscript. All the authors are accountable for all aspects of the work.

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Data availability

The dataset includes potentially identifiable or sensitive data, which, if disclosed publicly, could jeopardize the participants' privacy. Consequently, in compliance with the regulations established by the Danish Data Protection Agency, the data is not accessible to the public. However, interested parties may obtain access by making a reasonable request to the corresponding author.

Declarations

Ethics approval and consent to participate

Ethical approval from the Regional Scientific Ethical Committee was accepted and registered (H-21027110). The project was accepted and registered by the Danish Data Protection Agency (journal number: P-2021–38). The principles of the Declaration of Helsinki were followed. Before signing their informed consent, the patients were invited to a meeting held in a quiet room, where they were encouraged to bring a next of kin. Following the meeting, they were offered 3 days to consider their decision. While orally communicating information about the study, it was determined whether the patient fulfilled the criteria for participation. The patients were screened for eligibility according to the inclusion and exclusion criteria. Only after signing the informed consent form they were enrolled in the trial.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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